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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	SUROS-3
First Inventor	Michael E. Miller et al.
Title	BIOPSY APPARATUS
Express Mail Label No.	EI420927038US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. [X] Fee Transmittal Form (e.g., PTO/SB/17) *(Submit an original and a duplicate for fee processing)*
2. [X] Applicant claims small entity status. See 37 CFR 1.27.
3. [X] Specification *(preferred arrangement set forth below)* [*Total Pages* 57]
   - Descriptive title of the invention
   - Cross Reference to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to sequence listing, a table, or a computer program listing appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
4. [X] Drawing(s) *(35 U.S.C. 113)* [*Total Sheets* 6]
5. Oath or Declaration [*Total Pages*]
   a. [ ] Newly executed (original or copy)
   b. [ ] Copy from a prior application (37 CFR 1.63 (d)) *(for continuation/divisional with Box 17 completed)*
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. [ ] Application Data Sheet. See 37 CFR 1.76

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Box Patent Application
Washington, DC 20231

7. [ ] CD-ROM or CD-R in duplicate, large table or Computer Program *(Appendix)*
8. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   a. [ ] Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. [ ] CD-ROM or CD-R (2 copies); or
      ii. [ ] paper
   c. [ ] Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. [ ] Assignment Papers (cover sheet & document(s))
10. [ ] 37 CFR 3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
11. [ ] English Translation Document *(if applicable)*
12. [X] Information Disclosure Statement (IDS)/PTO-1449 [X] Copies of IDS Citations
13. [ ] Preliminary Amendment
14. [X] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
15. [ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. [ ] Other: .....

17. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:*

[ ] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No: _____/_____

Prior application information: *Examiner* _____ *Group / Art Unit:* _____

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

18. CORRESPONDENCE ADDRESS

[ ] *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* or [ ] *Correspondence address below*

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Signature	Deborah Beck	*Date*	November 6, 2000

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FEE TRANSMITTAL for FY 2000

Patent fees are subject to annual revision.
Small Entity payments must be supported by a small entity statement, otherwise large entity fees must be paid. See Forms PTO/SB/09-12. See 37 C.F.R §§ 1.27 and 1.28.

TOTAL AMOUNT OF PAYMENT ($) 635.00

Complete if Known	
Application Number	
Filing Date	November 6, 2000
First Named Inventor	Michael E. Miller, et al.
Examiner Name	
Group / Art Unit	
Attorney Docket No.	SUROS-3

METHOD OF PAYMENT (check one)

1. ☐ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

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Deposit Account Name: Baker & Daniels

☒ Charge Any Additional Fee Required Under 37 CFR §§ 1.16 and 1.17

2. ☒ **Payment Enclosed:** ☒ Check ☐ Money Order ☐ Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	690	201	345	Utility filing fee	355.00
106	310	206	155	Design filing fee	
107	480	207	240	Plant filing fee	
108	690	208	345	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($) 355.00

2. EXTRA CLAIM FEES

		Extra Claims		Fee from below	Fee Paid
Total Claims	13	-20** = 0	X	9	= 0
Independent Claims	10	- 3** = 7	X	40	= 280
Multiple Dependent					= 0

**or number previously paid, if greater; For Reissues, see below

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	78	202	39	Independent claims in excess of 3
104	260	204	130	Multiple dependent claim, if not paid
109	78	209	39	** Reissue independent claims over original patent
110	18	210	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 280.00

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	0.00
127	50	227	25	Surcharge - late provisional filing fee or cover sheet.	0.00
139	130	139	130	Non-English specification	0.00
147	2,520	147	2,520	For filing a request for reexamination	0.00
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	0.00
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	0.00
115	110	215	55	Extension for reply within first month	0.00
116	380	216	190	Extension for reply within second month	0.00
117	870	217	435	Extension for reply within third month	0.00
118	1,360	218	680	Extension for reply within fourth month	0.00
128	1,850	228	925	Extension for reply within fifth month	0.00
119	300	219	150	Notice of Appeal	0.00
120	300	220	150	Filing a brief in support of an appeal	0.00
121	260	221	130	Request for oral hearing	0.00
138	1,510	138	1,510	Petition to institute a public use proceeding	0.00
140	110	240	55	Petition to revive - unavoidable	0.00
141	1,210	241	605	Petition to revive - unintentional	0.00
142	1,210	242	605	Utility issue fee (or reissue)	0.00
143	430	243	215	Design issue fee	0.00
144	580	244	290	Plant issue fee	0.00
122	130	122	130	Petitions to the Commissioner	0.00
123	50	123	50	Petitions related to provisional applications	0.00
126	240	126	240	Submission of Information Disclosure Stmt	0.00
581	40	581	40	Recording each patent assignment per property (times number of properties)	0.00
146	690	246	345	Filing a submission after final rejection (37 CFR § 1.129(a))	0.00
149	690	249	345	For each additional invention to be examined (37 CFR § 1.129(b))	0.00
Other fee (specify)					0.00
Other fee (specify)					0.00

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 0.00

SUBMITTED BY				Complete (if applicable)	
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Signature	Deborah R. Beck			Date	Nov. 6, 2000

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Date:November 6, 2000 Attorney Docket No.: SUROS-3

BOX PATENT APPLICATION
Commissioner for Patents
Washington, D.C. 20231

Re: Application for United States Letters Patent

Applicant: Michael E. Miller, et al.

Title of Invention: BIOPSY APPARATUS

Sir:

Forwarded herewith is the above-identified application, consisting of the following:

Specification (57 Pages)
Claims (8 Pages)
Abstract of the Disclosure X
Drawings (6 sheets)
Declaration __ Executed X Unexecuted
Utility Patent Application Transmittal
Fee Transmittal
Information Disclosure Statement
References
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Check No. 195917 $635.00

Respectfully submitted,

Deborah Beck

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Registration No. 37,370
Attorney for Applicants

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BIOPSY APPARATUS

FIELD OF THE INVENTION

This invention relates to biopsy instruments and methods for taking a biopsy. More specifically, this invention relates to disposable biopsy devices for removing several tissue samples using a single insertion.

BACKGROUND OF THE INVENTION

In the diagnosis and treatment of breast cancer, it is often necessary to remove multiple tissue samples from a suspicious mass. The suspicious mass is typically discovered during a preliminary examination involving visual examination, palpitation, X-ray, MRI, ultrasound imaging or other detection means. When this preliminary examination reveals a suspicious mass, the mass must be evaluated by taking a biopsy in order to determine whether the mass is malignant or benign. Early diagnosis of breast cancer, as well as other forms of cancer, can prevent the

spread of cancerous cells to other parts of the body and ultimately prevent fatal results.

A biopsy can be performed by either an open procedure or a percutaneous method. The open surgical biopsy procedure first requires localization of the lesion by insertion of a wire loop, while using visualization technique, such as X-ray or ultrasound. Next, the patient is taken to a surgical room where a large incision is made in the breast, and the tissue surrounding the wire loop is removed. This procedure causes significant trauma to the breast tissue, often leaving disfiguring results and requiring considerable recovery time for the patient. This is often a deterrent to patients receiving the medical care they require. The open technique, as compared to the percutaneous method, presents increased risk of infection and bleeding at the sample site. Due to these disadvantages, percutaneous methods are often preferred.

Percutaneous biopsies have been performed using either Fine Needle Aspiration or core biopsy in conjunction with real-time visualization techniques, such as ultrasound or mammography (X-ray). Fine Needle Aspiration involves the removal of a small number of cells using an aspiration needle. A smear of the cells is

then analyzed using cytology techniques. Although Fine Needle Aspiration is less intrusive, only a small amount of cells are available for analysis. In addition, this method does not provide for a pathological assessment of the tissue, which can provide a more complete assessment of the stage of the cancer, if found. In contrast, in core biopsy a larger fragment of tissue can be removed without destroying the structure of the tissue. Consequently, core biopsy samples can be analyzed using a more comprehensive histology technique, which indicates the stage of the cancer. In the case of small lesions, the entire mass may be removed using the core biopsy method. For these reasons core biopsy is preferred, and there has been a trend towards the core biopsy method, so that a more detailed picture can be constructed by pathology of the disease's progress and type.

The first core biopsy devices were of the spring advanced, "Tru-Cut" style consisting of a hollow tube with a sharpened edge that was inserted into the breast to obtain a plug of tissue. This device presented several disadvantages. First, the device would sometimes fail to remove a sample, therefore, requiring additional insertions. This was generally due to tissue failing to prolapse into

the sampling notch. Secondly, the device had to be inserted and withdrawn to obtain each sample, therefore, requiring several insertions in order to acquire sufficient tissue for pathology.

The biopsy apparatus disclosed in U.S. Patent No. 5,526,822 to Burbank, et al was designed in an attempt to solve many of these disadvantages. The Burbank apparatus is a biopsy device that requires only a single insertion into the biopsy site to remove multiple tissue samples. The device incorporates a tube within a tube design that includes an outer piercing needle having a sharpened distal end for piercing the tissue. The outer needle has a lateral opening forming a tissue receiving port. The device has an inner cannula slidingly disposed within the outer cannula, and which serves to cut tissue that has prolapsed into the tissue receiving port. Additionally, a vacuum is used to draw the tissue into the tissue receiving port.

Vacuum assisted core biopsy devices, such as the Burbank apparatus, are available in handheld (for use with ultrasound) and stereotactic (for use with X-ray) versions. Stereotactic devices are mounted to a stereotactic unit that locates the lesion and positions the needle for insertion. In preparation for a biopsy using a

stereotactic device, the patient lies face down on a table, and the breast protrudes from an opening in the table. The breast is then compressed and immobilized by two mammography plates. The mammography plates create images that are communicated in real-time to the stereotactic unit. The stereotactic unit then signals the biopsy device and positions the device for insertion into the lesion by the operator.

In contrast, when using the handheld model, the breast is not immobilized. Rather the patient lies on her back and the doctor uses an ultrasound device to locate the lesion. The doctor must then simultaneously operate the handheld biopsy device and the ultrasound device.

Although the Burbank device presents an advancement in the field of biopsy devices, several disadvantages remain and further improvements are needed. For example, the inner cutter must be advanced manually, meaning the surgeon manually moves the cutter back and forth by lateral movement of a knob mounted on the outside of the instrument or by one of the three pedals at the footswitch. Also, the vacuum source that draws the tissue into the receiving port is typically supplied via a vacuum

chamber attached to the outer cannula. The vacuum chamber defines at least one, usually multiple, communicating holes between the chamber and the outer cannula. These small holes often become clogged with blood and bodily fluids. The fluids occlude the holes and prevent the aspiration from drawing the tissue into the receiving port. This ultimately prevents a core from being obtained, a condition called a "dry tap."

In addition, many of the components of the current biopsy devices are reusable, such as the driver portions, which control the outer and inner needles. This poses several notable disadvantages. First, the reusable portion must be cleaned and/or sterilized. This increases the time necessary to wrap up the procedure, which ultimately affects the cost of the procedure. In addition, the required clean-up and/or sterilization of reusable parts increases the staffs' potential exposure to body tissues and fluids. Finally, the reusable handle is heavy, large and cumbersome for handheld use.

A further disadvantage is that current biopsy devices comprise an open system where the tissue discharge port is simply an open area of the device. A surgical assistant must

remove the tissue from the open compartment using forceps and place the tissue on a sample plate. This ritual must be followed for every sample and, therefore, multiple operators are required. In addition, the open system increases the exposure to potentially infectious materials, and requires increased handling of the sample. As a practical matter, the open system also substantially increases the clean-up time and exposure, because a significant amount of blood and bodily fluid leaks from the device onto the floor and underlying equipment.

Additionally, when using the current biopsy devices, physicians have encountered significant difficulties severing the tissue. For instance, the inner cutter often fails to completely sever the tissue. When the inner cutting needle is withdrawn, no tissue sample is present (dry tap), and therefore, reinsertion is required. In the case of the Burbank apparatus, the failure to completely sever the tissue after the first advancement of the inner cutter results in a necessary second advancement of the inner cutter. In this event, the procedure is prolonged, which is significant because the amount of trauma to the tissue and, ultimately, to the patient is greatly affected by the length of the procedure. Therefore, it is in

the patient's best interest to minimize the length of the procedure by making each and every attempt at cutting the tissue a successful and complete cut.

Additionally, when using the "tube within a tube" type biopsy device, the inner cutter can lift up into the tissue receiving opening during cutting. This lifting causes the inner cutter to catch on the edge of the tissue receiving opening, which ultimately results in an incomplete cut and dulling of the blade, rendering the blade useless.

Also, prior devices often produce small tissue samples. As the inner cutter advances, the cutting edge not only starts to sever the tissue, it also pushes the tissue in front of the cutter. This results in a tissue sample that is smaller than the amount of tissue drawn into the tissue receiving opening.

An additional disadvantage of the prior devices is presented by the complexity of the three-pedal footswitch. Prior devices utilized a three-pedal footswitch; one pedal for advancing the inner cannula, another pedal for retracting the inner cannula, and a third pedal for turning on the aspiration. Operation of the three pedals is difficult and awkward.

These disadvantages become even more significant when using the handheld biopsy device. For instance, the physician must operate the biopsy device and the ultrasound probe simultaneously making it particularly difficult to manually advance of the inner cutter. In addition, when an assistant is required to remove each sample from the open discharge port, use of the handheld device becomes even more awkward. Due to these disadvantages, many physicians have declined to use the handheld models.

This is unfortunate because, some lesions that can signify the possible presence of cancer cannot be seen using the stereotactic unit. In these cases, the doctor must resort to either the handheld device or open surgical biopsy. Due to the difficulties associated with the handheld device, doctors often choose the open surgical biopsy, which is particularly unfortunate because a majority of the lesions that cannot be seen using the stereotactic unit turn out to be benign. This means that the patient has unnecessarily endured a significant amount of pain and discomfort; not to mention extended recovery time and disfiguring results. In addition, the patient has likely incurred a greater financial expense

because the open surgical technique is more difficult, time consuming and costly, especially for those patient without health insurance.

The disadvantages of the open surgical technique coupled with the odds that the lesion is benign present a disincentive for the patient to consent to the biopsy. The added discomfort alone is enough to cause many patients to take the risk that the lesion is benign. The acceptance of this risk can prove to be fatal for the minority of cases where the lesion is malignant.

Finally, current vacuum assisted biopsy devices are not capable of being used in conjunction with MRI. This is due to the fact that many of the components are made of magnetic components that interfere with the operation of the MRI. It would be desirable to perform biopsies in conjunction with MRI because it currently is the only non-invasive visualization modality capable of defining the margins of the tumor.

In light of the foregoing disadvantages, a need remains for a tissue removal device that reliably applies a vacuum without becoming plugged with blood and bodily fluids. A need also remains for a tissue removal device that is entirely disposable so

that both exposure to bio-hazard and clean-up time are significantly minimized, while convenience is maximized. A further need remains for a tissue removal device that completely severs the maximum amount of tissue without requiring numerous attempts at cutting the tissue. A need also remains for a tissue removal device that is MRI compatible. Finally, a need remains for a biopsy tissue removal device that is completely automated, therefore making the handheld biopsy device a more efficient and attractive option.

SUMMARY OF THE INVENTION

The present invention fulfills the aforementioned needs by providing a disposable tissue removal device comprising a cutting element mounted to a handpiece. The cutting element includes an outer cannula defining a tissue-receiving opening and an inner cannula concentrically disposed within the outer cannula.

The outer cannula has a trocar tip at its distal end and a cutting board snugly disposed within the outer cannula. The inner cannula defines an inner lumen that extends the length of the inner cannula, and which provides an avenue for aspiration. The inner cannula terminates in an inwardly beveled, razor-sharp cutting edge and is driven by, both a rotory motor, and a reciprocating motor. As the inner cannula moves past the tissue-receiving opening, the inwardly beveled edge helps to eliminate the risk of catching the edge on the tissue-receiving opening. At the end of its stroke, the inner cannula makes contact with the cutting board to completely sever the tissue. The cutting board is made of a material that is mechanically softer than the cutting edge yet hard enough to withstand the force of the inner cannula.

An aspiration is applied to the inner lumen through an aspiration tube. The aspiration tube communicates with a collection trap that is removably mounted to the handpiece. The aspiration draws the sample into the tissue-receiving opening and after the tissue is cut, draws the tissue through the inner cannula to a collection trap.

In a specific embodiment, both the rotary motor and the reciprocating motors are hydraulic motors. Because hydraulic motors do not require any electrical components, this feature allows all of the components to be fabricated of MRI compatible materials.

In another embodiment, the tissue-receiving opening is formed by opposite longitudinal edges that form a number of teeth. The teeth face away from the cutting board at the distal end of the outer cannula. The teeth help prevent the forward motion of the tissue in the opening as the inner cannula moves forward toward the cutting board. This feature maximizes the length and overall size of the core, ultimately resulting in a more efficient lesion removal.

In another embodiment, the outer cannula incorporates a stiffening element opposite the tissue-receiving opening. This stiffening element aids in maintaining the longitudinal integrity of the outer cannula as it is advanced through the tissue.

In addition to the inwardly beveled edge of the inner cannula, one embodiment incorporates additional features to prevent the inner cannula from rising up into the tissue-receiving opening. A bead of stiffening material may be affixed to the inner wall of the outer cannula, or a dimple may be formed in the inner wall of the outer cannula. The bead, or dimple urges the inner cannula away from the tissue-receiving opening and prevents the inner cannula from catching on the opening.

DESCRIPTION OF THE FIGURES

FIG. 1 is a top perspective view of a tissue biopsy apparatus in accordance with one embodiment of the present invention.

FIG. 2 is a top elevational view of the tissue biopsy apparatus shown in **FIG. 1**.

FIG. 3A and **FIG. 3B** are side cross-sectional views of the tissue biopsy apparatus depicted in **FIGS. 1** and **2**, with the tissue cutting inner cannula shown in its retracted and extended positions.

FIG. 4 is a perspective view of a cover for the tissue biopsy apparatus as shown **FIG. 1**.

FIG. 5 is an enlarged side cross-sectional view of the operating end of the tissue biopsy apparatus depicted in **FIGS. 1** and **2.**

FIG. 6 is a side partial cross-sectional view of working end of a tissue biopsy apparatus in accordance with an alternative embodiment.

FIG. 7 is an end cross-sectional view of the apparatus depicted in **FIG. 6**, taken along lines 7-7 as viewed in the direction of the arrows.

FIG. 8 is an end cross-sectional view similar to **FIG. 7** showing a modified configuration for a stiffening member.

FIG. 8(a) is an end cross-sectional view similar to **FIG. 7** showing a modified configuration for another stiffening member.

FIG. 9 is an enlarged side cross-sectional view of a fluid introduction port at the hub connecting the outer cannula to the handpiece for a tissue biopsy apparatus as depicted in **FIG. 1**.

FIG. 10 is a schematic drawing of the hydraulic control system for the operation of the tissue biopsy apparatus shown in **FIG. 1**.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. The invention includes any alterations and further modifications in the illustrated devices and described methods and further applications of the principles of the invention which would normally occur to one skilled in the art to which the invention relates.

A tissue biopsy apparatus **10** in accordance with one embodiment of the present invention is shown in **FIGS. 1-5**. The apparatus **10** includes a cutting element **11** mounted to a handpiece **12**. The cutting element **11** is sized for introduction into a human body. Most particularly, the present invention concerns an apparatus for excising breast tissue samples. Thus, the cutting element **11** and the overall biopsy apparatus **10** are configured for ease of use in this surgical environment. In the illustrated embodiment, the biopsy apparatus **10** is configured as a hand-held device. However, the same inventive principles can be employed in a tissue biopsy apparatus that is used stereotatically in which the apparatus is mounted on a support fixture that is used to position the cutting element **11** relative to the tissue to be sampled.

Nevertheless, for the purposes of understanding the present invention, the tissue biopsy apparatus will be described as a hand-held device.

The cutting element **11** is configured as "tube-within-a-tube" cutting device. More specifically, the cutting element **11** includes an outer cannula **15** terminating in a tip **16**. Preferably, the tip is a trocar tip that can be used to penetrate the patient's skin. Alternatively, the tip **16** can simply operate as a closure for the open end of the cannula **15**. In this instance, a separate introducer would be required.

The cutting element **11** further includes an inner cannula **17** that fits concentrically within the outer lumen **27** (**FIG. 5**) of the outer cannula **15**. In the most preferred embodiment, both a rotary motor **20** (**FIG. 1**) and a reciprocating motor **22** drive the inner cannula **17**. Both motors are supported within the handpiece **12**. Again, in accordance with the preferred embodiment the rotary motor **20** and reciprocating motor **22** are configured for simultaneous operation to translate the inner cannula **17** axially within the outer cannula **15**, while rotating the inner cannula **17** about its longitudinal axis.

One specific configuration of the working end of the cutting element **11** is depicted in **FIG. 5**. The outer cannula **15** defines a

tissue-receiving opening **25**, which communicates with the outer lumen **27**. A pair of opposite longitudinal edges **26** (**FIGS. 1** and **2**) define the tissue-receiving opening **25**. The outer cannula **15** is open at its distal end **28** with the trocar tip **16** engaged therein. Preferably, the trocar tip **16** forms an engagement hub **30** that fits tightly within the distal end **28** of the outer cannula **15**. The hub **30** can be secured by welding, press-fit, adhesive or other means suitable for a surgical biopsy instrument.

The working end of the cutting element **11** further includes a cutting board **31** that is at least snugly disposed within the outer lumen **27** at the distal end **28** of the outer cannula **15**. Most preferably, the cutting board **31** is in direct contact with the engagement hub **30** of the trocar tip **16**. The cutting board **31** can be permanently affixed within the outer cannula **15** and/or against the engagement hub **30** of the trocar tip.

The inner cannula **17** defines an inner lumen **34** that is hollow along the entire length of the cannula to provide for aspiration of the biopsy sample. The inner cannula **17** terminates in a cutting edge **35**. Preferably the cutting edge **35** is formed by an inwardly beveled surface **36** to provide a razor-sharp edge. The inwardly beveled surface helps eliminate the risk of catching the edge **35** on the tissue-receiving opening **25** of the outer cannula. In addition, the beveled surface **36** helps avoid pinching

the biopsy material between the inner and outer cannulas during a cutting stroke.

In a specific embodiment, both the outer cannula **15** and the inner cannula **17** are formed of a surgical grade metal. Most preferably, the two cannulae are formed of stainless steel. In the case of an MRI compatible device, the cannulae can be formed of Inconel, Titanium or other materials with similar magnetic characteristics. Likewise, the trocar tip **16** is most preferably formed of stainless steel honed to a sharp tip. The trocar tip **16** can be suitably bounded to the outer cannula **15**, such as by welding or the use of an appropriate adhesive.

The cutting board **31** is formed of a material that is configured to reduce the friction between the cutting edge **35** of the inner cannula **17** and the cutting board **31**. The cutting edge **35** necessarily bears against the cutting board **31** when the inner cannula **17** is at the end of its stroke while severing a tissue sample. Since the inner cannula is also rotating, the cutting edge necessarily bears directly against the cutting board **31**, particularly after the tissue sample has been cleanly severed. In prior devices, the impact-cutting surface has been formed of the same material as the cutting element. This leads to significant wear or erosion of the cutting edge. When numerous cutting cycles are to be performed, the constant wear on the cutting edge eventually renders it incapable of cleanly severing a tissue sample.

Thus, the present invention contemplates forming the cutting board **31** of a material that reduces this frictional wear. In one embodiment, the cutting board **31** is formed of a material that is mechanically softer than the material of the cutting edge **35**. However, the cutting board **31** cannot be so soft that the cutting edge **35** forms a pronounced circular groove in the cutting board, which significantly reduces the cutting efficiency of the inner cannula. In a most preferred embodiment of the invention, the cutting board **31** is formed of a plastic material, such as polycarbonate, ABS or DELRIN®.

Returning again to **FIGS. 1, 2** and **3A – 3B,** the rotary motor **20** includes a motor housing **39** that is sized to reciprocate within the handpiece **12**. The housing **39** defines a pilot port **40** that is connected to the hydraulic control system **150** (see **FIG. 10**) by appropriate tubing. The present invention contemplates that the motor **20** can be a number of hydraulically powered rotating components. Most preferably, the motor **20** is an air motor driven by pressured air. Thus, the motor **20** includes a vaned rotor **42** that is mounted on a hollow tubular axle **43** extending through the motor housing **39**. The axle **43** is supported on bearings **44** at opposite ends of the housing so that the rotor **42** freely rotates within the motor housing **39** under pneumatic pressure.

In the illustrated embodiment, tubular axle **43** is connected to the proximal end **37** of the inner cannula **17** by way of a coupler **46**. The ends of the two tubes are mounted within the coupler **46** and held in place by corresponding set screws **47**. Preferably the coupler **46** is formed of a plastic material that provides a generally airtight seal around the joint between the inner cannula **17** and the tubular axle **43**. It is important that the coupler **46** provide a solid connection of the inner cannula **17** to the rotating components of the motor **20** so that the inner cannula **17** does not experience any torrential slip during the cutting operation.

Since the inner cannula **17** provides an avenue for aspiration of the biopsy sample, the invention further contemplates an aspiration tube **50** that mates with the tubular axle **43**. Thus, the tissue aspiration path from the working end of the cutting element **11** is along the inner lumen **34** of the inner cannula **17**, through the tubular axle **43** of the rotary motor **20**, and through the aspiration tube **50** to a tissue collection location in the form of a collection trap **55**. In order to maintain the vacuum or aspiration pressure within this aspiration path, the aspiration tube **50** must be fluidly sealed against the tubular axial **43**. Thus, the motor housing **39** defines a mounting hub **51** into which the aspiration tube **50** is engaged. The position of the aspiration tube **50** is fixed by way of a setscrew **52** passing through the mounting hub **51**. In contrast to the joint between the inner cannula **17** and the tubular axial **43**, the joint between the aspiration tube **50** and the tubular axial **43** allows

relative rotational between the two components. The tubular axle **43**, of course, rotates with the rotor **42**. However, the aspiration tube **50** need not rotate for use with the biopsy apparatus of the present invention. The mounting hub **51** can include an arrangement of seal rings (not shown) at the joint between the aspiration tube **50** and the tubular axle **43** to further seal the aspiration system.

The aspiration tube **50** communicates with a collection trap **55** that is removably mounted to the handpiece **12**. The collection trap **55** includes a pilot port **107** that is connected by appropriate tubing to the hydraulic control system **150**, as described in more detail herein. For the present purposes, it is understood that a vacuum or aspiration pressure is drawn through the pilot port **107** and the collection trap **55**. This vacuum then draws a tissue sample excised at the working end of the cutting element **11**, all the way through the inner cannula **17**, tubular axle **43** and aspiration tube **50** until it is deposited within the trap. Details of the collection trap **55** will be discussed herein.

As explained above, the present invention contemplates an inner cannula **17** that performs its cutting operation by both rotary and reciprocating motion. Thus, the handpiece **12** supports a reciprocating motor **22**. In one aspect of the invention, both motors **20** and **22** are hydraulically powered, most preferably pneumatically. This feature allows the motors to be formed of

plastic, since no electrical components are required. In fact, with the exception of the outer cannula **15**, trocar tip **16** and inner cannula **17**, every component of the biopsy apparatus **10** in accordance with the present invention can be formed of a non-metallic material, most preferably a medical grade plastic. Thus, the biopsy apparatus **10** is eminently compatible with surgical imaging systems that may be used during the biopsy procedure. The compatibility of the apparatus **10** with Magnetic Resonance Imaging (MRI) is important because MRI is currently the only non-invasive visualization modality capable of defining the margins of the tumor. In addition, since the biopsy apparatus is formed of a relatively inexpensive plastic (as opposed to a more expensive metal), the entire apparatus can be disposable. Moreover, the elimination of substantially all metal components reduces the overall weight of the handpiece **12**, making it very easily manipulated by the surgeon.

Referring most specifically to **FIGS. 3A** and **3B**, the reciprocating motor **22** includes a pneumatic cylinder **60**. The cylinder **60** includes a pilot port **61** that connects the cylinder to the hydraulic control system **150** through appropriate tubing. The motor **22** includes a piston **63** that reciprocates within the cylinder **60** in response to hydraulic fluid pressure provided at the pilot port **61**. The piston **63** includes a central bore **64** for mounting the piston **63** to the aspiration tube **50**. In one embodiment, the aspiration tube **50** is press-fit within the bore **64**. The engagement

between the aspiration tube **50** and the piston **63** can be enhanced by use of a set screw (not shown) or an adhesive or epoxy. At any rate, it is essential that the aspiration tube **50** and piston **63** move together, since the motor **22** must eventually drive the inner cannula **17** axially within the outer cannula.

It should be understood that in addition to powering the inner cannula, the piston **63** also reciprocates the rotary motor **20**, which is essentially mounted to the reciprocating aspiration conduit. This movement is depicted by comparing the position of the rotary motor **20** between **FIG. 3A** and **FIG. 3B**. More specifically, the motor **20** as well as the aspiration conduit, including the inner cannula **17**, moves within the handpiece **12**. Preferably, the handpiece housing **70** is provided with openings **73** (**FIG. 3B**) at its opposite ends for slidably supporting the aspiration tube **50** and inner cannula **17**. Since the distal housing **70** is preferably formed of a plastic material, no thrust bearings or rotary bearings are necessary to accommodate low friction axial movement of the cannula through the housing openings **73**.

The biopsy apparatus **10** includes a handpiece **12** that carries all of the operating components and supports the outer and inner cannulas. The handpiece **12** includes a distal housing **70** within which is disposed the rotary motor **20**. The distal end **71** of the housing **70** is configured into a fitting **72**. This fitting **72** engages a mating flange **77** on an outer cannula hub **75**. The hub

75 supports the outer cannula **15** within an engagement bore **76** (see **FIG. 3B**).

In accordance with one aspect of the present invention, the engagement between the outer cannula hub **75** and the distal end **71** of the housing **70** need not be airtight. In other words, the mating components of the fitting between the two parts need not be capable of generating a fluid-tight seal. In accordance with one embodiment of the invention, the engagement between the hub **75** and the housing **70** for supporting the outer cannula **15** provides a leak path through the outer lumen **27** to the atmosphere. In the use of the tissue biopsy apparatus **10**, providing aspiration through the inner lumen **34** of the inner cutting cannula **17** will draw tissue through the inner lumen. As the tissue advances farther along the lumen, in some instances a vacuum can be created behind the advancing tissue. At some point in these instances, the tissue will stop advancing along the length of the inner lumen because the vacuum behind the tissue sample equals the vacuum in front of the tissue sample that is attempting to draw the sample to the collection trap **55**. Thus, the leak path through the outer lumen **27** allows atmospheric air to fall in behind the tissue sample when the inner cutter is retracted from the cutting board. The atmospheric air helps to relieve the vacuum behind the advancing tissue and aids in drawing the tissue down the length of the aspiration channel to the collection trap **55**. However, in some applications,

particularly where smaller "bites" of the target tissue are taken, the atmospheric air leak path is not essential.

Preferably the fitting **72** and the mating flange **77** can be engaged by simple twisting motion, most preferably via Luer-type fittings. In use, the cannula hub **75** is mounted on the handpiece **12**, thereby supporting the outer cannula **15**. The handpiece can then be used to project the outer cannula into the body adjacent the sample site. In certain uses of the biopsy apparatus **10**, it is desirable to remove the handpiece **12** from the cannula hub **75** leaving the outer cannula **15** within the patient. For example, the outer cannula **15** can be used to introduce an anesthetic. In other applications, once the target tissue has been completely excised, the outer cannula can be used to guide a radio-opaque marker to mark the location the removed material.

Returning again to the description of the housing **70**, the housing defines an inner cavity **79** that is open through an access opening **81**. The access opening **81** is preferably provided to facilitate assembly of the tissue biopsy apparatus **10**. The distal end **71** of the housing **70** can be provided with a pair of braces **81** that add stiffness to the distal end **71** while the apparatus is in use. The braces **80** allow the distal housing **70** to be formed as a thin-walled plastic housing. Similar braces can be provided at the opposite end of the distal housing as necessary to add stiffness to the housing.

The distal housing is configured to support the reciprocating motor **22** and in particular the cylinder **60**. Thus, in one embodiment of the invention, the proximal end **83** of the distal housing **70** defines a pressure fitting **84**. It is understood that this pressure fitting **84** provides a tight leak-proof engagement between the distal end **88** of the cylinder **60** and the proximal end **83** of the housing. In one specific embodiment, the pressure fitting **84** forms a spring cavity **85** within which a portion of the return spring **66** rests. In addition, in a specific embodiment, the pressure fitting **84** defines distal piston stop **86**. The piston **63** contacts these stops at the end of its stroke. The location of the piston stop **86** is calibrated to allow the cutting edge **35** to contact the cutting board **31** at the working end of the cutting element **11** to allow the cutting edge to cleanly sever the biopsy tissue.

In the illustrated embodiment, the cylinder **60** is initially provided in the form of an open-ended cup. The open end, corresponding to distal end **88**, fastens to the pressure fitting **84**. In specific embodiments, the pressure fitting can include a threaded engagement, a press-fit or an adhesive arrangement.

The cylinder cup thus includes a closed proximal end **89**. This proximal end defines the pilot port **61**, as well as a central opening **62** (**FIG. 3B**) through which the aspiration tube **50** extends. Preferably, the proximal end **89** of the cylinder **60** is

configured to provide a substantially airtight seal against the aspiration tube **50** even as it reciprocates within the cylinder due to movement of the piston **63**. The proximal end **89** of the cylinder **60** defines a proximal piston stop **90**, which can either be adjacent the outer cylinder walls or at the center portion of the proximal end. This proximal piston stop **90** limits the reverse travel of the piston **63** under action of the return spring **66** when pressure within the cylinder has been reduced.

In a further aspect of the invention, the collection trap **55** is mounted to the handpiece **12** by way of a support housing **93**. It should be understood that in certain embodiments, the handpiece **12** can be limited to the previously described components. In this instance, the collection trap **55** can be situated separate and apart from the handpiece, preferably close to the source of vacuum or aspiration pressure. In this case, the proximal end of the aspiration tube **50** would be connected to the collection trap by a length of tubing. In the absence of the collection trap **55**, the aspiration tube **50** would reciprocate away from and toward the proximal end of the cylinder **60**, so that it is preferable that the handpiece includes a cover configured to conceals the reciprocating end of the aspiration tube.

However, in accordance with the most preferred embodiment, the collection trap **55** is removably mounted to the handpiece **12**. A pair of longitudinally extending arms **94**, that

define an access opening **95** therebetween, forms the support housing **93**. The support housing **93** includes a distal end fitting **96** that engages the proximal end **89** of cylinder **60**. A variety of engagements are contemplated, preferably in which the connection between the two components is generally airtight. The proximal end **97** of the support housing **93** forms a cylindrical mounting hub **98**. As best shown in **FIG. 1**, the mounting hub **98** surrounds a proximal end of the collection trap **55**. The hub forms a bayonet-type mounting groove **99** that receives pins **103** attached to the housing **102** of the trap **55**. A pair of diametrically opposite wings **104** can be provided on the housing **102** to facilitate the twisting motion needed to engage the bayonet mount between the collection trap **55** and the support housing **93**. While the preferred embodiment contemplates a bayonet mount, other arrangements for removably connecting the collection trap **55** to the support housing **93** are contemplated. To be consistent with one of the features of the invention, it is preferable that this engagement mechanism be capable of being formed in plastic.

In order to accommodate the reciprocating aspiration tube, the support housing **93** is provided with an aspiration passageway **100** that spans between the proximal and distal ends of the housing. Since the aspiration tube **50** reciprocates, it preferably does not extend into the collection trap **55**. As excised tissue is drawn into the trap **55**, a reciprocating aspiration tube **50** can contact the biopsy material retained within the trap. This

movement of the tube can force tissue into the end of the tube, clogging the tube. Moreover, the reciprocation of the aspiration tube can compress tissue into the end of the trap, thereby halting the aspiration function.

The collection trap **55** includes a housing **102**, as previously explained. The housing forms a pilot port **107**, which is connectable to a vacuum generator. Preferably in accordance with the present invention, appropriate tubing to the hydraulic control system 150 connects the pilot port **107**. The trap **55** includes a filter element **110** mounted within the trap. In the preferred embodiment, the filter element is a mesh filter than allows ready passage of air, blood and other fluids, while retaining excised biopsy tissue samples, and even morcellized tissue. In addition, the filter element **110** is preferably constructed so that vacuum or aspiration pressure can be drawn not only at the bottom end of the filter element, but also circumferencially around at least a proximal portion of the element **110**. In this way, even as material is drawn toward the proximal end of the filter, a vacuum can still be drawn through other portions of the filter, thereby maintaining the aspiration circuit.

The handpiece **12** can include individual covers for closing the access opening **81** in the distal housing **70** and the access openings **95** in the support housing **93**. Those covers can support tubing for engagement with the pilot ports **40** and **61**. Alternatively

and most preferably, a single cover **13** as depicted in **FIG. 4**, is provided for completely enclosing the entire handpiece. The distal end **71** of the housing **70** can define a number of engagement notches **115** equally spaced around the perimeter of the distal end. The handpiece cover **13** can then include a like number of equally distributed tangs **117** projecting inwardly from the inner surface from the **118**. These tangs are adapted to snap into the engagement notches **115** to hold the cover **113** in position over the handpiece **12**. The cover can be attached by sliding axially over the handpiece **12**. The cover **13** can include fittings for fluid engagement with the two pilot ports **40** and **61**. Alternatively, the cover can be formed with openings for insertion of engagement tubing to mate with the respective pilot ports to provide hydraulic fluid to the rotary motor **20** and the reciprocating motor **22**. In a specific embodiment, the cover **13** extends from the distal end **71** of the distal housing **70** to the proximal end **97** of the support housing **93**. The cover can thus terminate short of the bayonet mounting feature between the support housing and the collection trap **55**. Although not shown in the figures, the proximal end **97** of the support housing **93** can be configured to include a similar array of engagement notches with a corresponding array of mating tangs formed at the proximal end of the cover **13**.

Referring now to **FIGS. 6-8**, alternative embodiments of the outer cannula are depicted. As shown in **FIG. 6** an outer cannula **125** includes a tissue-receiving opening **126.** The opening is

formed by opposite longitudinal edges **127**. In one specific embodiment, a number of teeth **129** are formed at each longitudinal edge **127**. As depicted in the figure, the teeth are proximally facing – i.e., away from the cutting board **31** (not shown) at the distal end of the outer cannula. With this orientation, the teeth **129** help prevent forward motion of tissue drawn into the opening **126** as the inner cannula **17** moves forward toward the cutting board. In prior devices, as the reciprocating cutting element advances through the outer cannula, the cutting edge not only starts to sever the tissue, it also pushes tissue in front of the inner cannula. Thus, with these prior devices, the ultimate length of the biopsy sample retrieved with the cut is smaller than the amount of tissue drawn into the tissue-receiving opening of the outer cannula. With the teeth **129** of the outer cannula **125** of this embodiment of the invention, the tissue sample removed through the inner cannula **17** is substantially the same length as the tissue-receiving opening **126**. As the inner cannula **17** advances into the tissue, each of the teeth **129** tends to hold the tissue in place as the cutting edge **35** severs the tissue adjacent the outer cannula wall. With this feature, each "bite" is substantially as large as possible so that a large tissue mass can be removed with much fewer "bites" and in a shorter period of time. In addition to supporting the subject tissue as the inner cannula advances, the teeth can also cut into the tissue to prevent it from retracting out of the opening as the inner cutting cannula **17** advances.

The outer cannula **125** depicted in **FIG. 6** can also incorporate a stiffening element **131** opposite the tissue-receiving opening **126**. The stiffening element **131** adds bending stiffness to the outer cannula **125** at the distal end in order to maintain the longitudinal integrity of the outer cannula **125** as it is advanced into a tissue mass. In some prior devices that lack such a stiffening element, the working end of the cutting device is compromised as it bends slightly upward or downward as the outer cannula passes into the body. This bending can either close or expand the tissue-receiving opening, which leads to difficulties in excising and retrieving a tissue sample. The cutting mechanism of the present invention relies upon full, flush contact between the cutting edge of the inner cannula **17** and the cutting board **31**. If the end of the outer cannula **125** is slightly askew, this contact cannot be maintained, resulting in an incomplete slice of the tissue sample.

As depicted in the cross-sectional view of the **FIG. 7**, the stiffening element **131** in one embodiment is a crimp extending longitudinally in the outer wall of the cannula substantially coincident with the tissue-receiving opening **126**. The outer cannula **125'** depicted in **FIG. 8** shows two additional versions of a stiffening element. In both cases, a bead of stiffening material is affixed to the outer cannula. Thus in one specific embodiment, a bead **131'** is adhered to the inner wall of the outer cannula. In a second specific embodiment, a bead **131"** is affixed to the outside of the outer cannula. In either case, the beads can be formed of a

like material with the outer cannula, and in both cases, the beads provide the requisite additional bending stiffness. Another version of a stiffening element is shown if **FIG. 8(a)**. In this case, a layer **131'''** of additional stainless steel is bonded to the outer wall of the outer cannula **125"**.

Returning to **FIG. 6**, a further feature that can be integrated into the outer cannula **125** is the dimple **135**. One problem frequently experienced by tube-within-a-tube cutters is that the inner reciprocating cutter blade contacts or catches on the outer cannula at the distal edge of the tissue-receiving opening. With the present invention, the dimple **135** urges the inner cannula **17** away from the tissue-receiving opening **126**. In this way, the dimple prevents the cutting edge of the inner cannula **17** from catching on the outer cannula as it traverses the tissue-receiving opening. In the illustrated embodiment of **FIG. 6**, the dimple **135** is in the form of a slight crimp in the outer cannula **125**. Alternatively, as with the different embodiments of the stiffening element, the dimple **135** can be formed by a protrusion affixed or adhered to the inner surface of the outer cannula. Preferably, the dimple **135** is situated immediately proximal to the tissue-receiving opening to help maintain the distance between the cutting edge and the tissue-receiving opening.

As previously described, the outer cannula **15** is supported by a hub **75** mounted to the distal end of the handpiece. In an

alternative embodiment depicted in **FIG. 9**, the outer cannula hub **140** provides a mean for introducing fluids into the outer lumen **27** of the outer cannula. Thus, the hub **140** includes an engagement bore **141** within which the outer cannula **15** is engaged. The hub also defines a flange **142** configured for mating with the fitting **72** at the distal end **71** of the housing **70**. Thus, the outer cannula hub **140** is similar to the hub **75** described above. With this embodiment, however, an irrigation fitting **145** is provided. The fitting defines an irrigation lumen **146** that communicates with the engagement bore **141**.

Ultimately, this irrigation lumen is in fluid communication with the outer lumen **27** of the outer cannula **15**. The irrigation fitting **145** can be configured for engagement with a fluid-providing device, such as a syringe. The hub **140** thus provides a mechanism for introducing specific fluids to the biopsy site. In certain procedures, it may be necessary to introduce additional anesthetic to the sampling site, which can be readily accommodated by the irrigation fitting **145**.

As discussed above, the preferred embodiment of the tissue biopsy apparatus **10** according to the present invention relies upon hydraulics or pneumatics for the cutting action. Specifically, the apparatus includes a hydraulic rotary motor **20** and a hydraulic reciprocating motor **22.** While the apparatus **10** can be adapted for taking a single biopsy slice, the preferred use is to completely

remove a tissue mass through successive cutting slices. In one typical procedure, the cutting element **11** is positioned directly beneath a tissue mass, while an imaging device is disposed above the mass. The imaging device, such as an ultra-sound imager, provides a real-time view of the tissue mass as the tissue biopsy apparatus **10** operates to successively remove slices of the mass. Tissue is continuously being drawn into the cutting element **11** by the aspiration pressure or vacuum drawn through the inner cannula **17**. Successive reciprocation of the inner cannula **17** removes large slices of the mass until it is completely eliminated.

In order to achieve this continuous cutting feature, the present invention contemplates a hydraulic control system **150**, as illustrated in the diagram of **FIG. 10**. Preferably the bulk of the control system is housed within a central console. The console is connected to a pressurized fluid source **152**. Preferably the fluid source provides a regulated supply of filtered air to the control system **150**.

As depicted in this diagram of **FIG. 10**, pressurized fluid from the source as provided at the several locations **152** throughout the control system. More specifically, pressurized fluid is provided to five valves that form the basis of the control system.

At the left center of the diagram of **FIG. 10**, pressurized fluid **152** passes through a pressure regulator **154** and gauge **155**. The

gauge **155** is preferably mounted on the console for viewing by the surgeon or medical technician. The pressure regulator **154** is manually adjustable to control the pressurized fluid provided from the source **152** to the two-position hydraulic valve **158.** The valve **158** can be shifted between a flow path **158a** and a flow path **158b**. A return spring **159** biases the hydraulic valve to its normal position **158a**.

In the normally biased position of flow path **158a**, the valve **158** connects cylinder pressure line **161** to the fluid source **152**. This pressure line **161** passes through an adjustable flow control valve **162** that can be used to adjust the fluid flow rate through the pressure line **161**. Like the pressure gauge **155** and pressure regulator **154**, the adjustable flow control valve **162** can be mounted on a console for manipulation during the surgical procedure.

The pressure line **161** is connected to the pilot port **61** of the reciprocating motor **22**. Thus, in the normal or initial position of the hydraulic control system **150**, fluid pressure is provided to the cylinder **60** to drive the piston **63** against the biasing force of the return spring **66**. More specifically with reference to **FIG. 3B**, the initial position of the hydraulic valve **158** is such that the reciprocating motor and inner cannula are driven toward the distal end of the cutting element. In this configuration, the inner cannula **17** covers the tissue-receiving opening **25** of the outer cannula **15**.

With the inner cannula so positioned, the outer cannula can be introduced into the patient without risk of tissue filling the tissue-receiving opening **25** prematurely.

Pressurized fluid along cylinder pressure **161** is also fed to a pressure switch **165**. The pressure switch has two positions providing flow paths **165a** and **165b**. In addition, an adjustable return spring **166** biases this switch to its normal position at which fluid from the pressure source **152** terminates within the valve. However, when pressurized fluid is provided through cylinder pressure line **161**, the pressure switch **165** moves to its flow path **165b** in which the fluid source **152** is hydraulically connected to the pressure input line **168**. This pressure input line **168** feeds an oscillating hydraulic valve **170**. It is this valve that principally operates to oscillate the reciprocating motor **22** by alternately pressurizing and releasing the two-position hydraulic valve **158**. The pressure switch **165** is calibrated to sense an increase in pressure within the cylinder pressure line **161** or in the reciprocating motor cylinder **60** that occurs when the piston **66** has reached the end of its stroke. More specifically, the piston reaches the end of its stroke when the inner cannula **17** contacts the cutting board **31**. At this point, the hydraulic pressure behind the piston increases, which increase is sensed by the pressure valve **165** to stroke the valve to the flow path **165b**.

The oscillating hydraulic valve **170** has two positions providing flow paths **170a** and **170b**. In position **170a**, input line **179** is fed to oscillating pressure output line **172**. With flow path **170b**, the input line **179** is fed to a blocked line **171**. Thus, with fluid pressure provided from pressure switch **165** (through flow path **165b**), the oscillating valve **170** opens flow path **170a** which completes a fluid circuit along output line **172** to the input of the hydraulic valve **158**.

Fluid pressure to output line **172** occurs only when there is fluid pressure within input line **179**. This input line is fed by valve **176**, which is operated by foot pedal **175**. The valve **176** is biased by a return spring **177** to the initial position of flow path **176a**. However, when the foot pedal **175** is depressed, the valve **176** is moved against the force of the spring to flow path **176b**. In this position, pressurized fluid from the source **152** is connected to the foot pedal input line **179**. When the oscillating hydraulic valve **170** is in its initial position flow path **170a,** pressurized fluid then flows through input line **179** to output line **172** and ultimately to the hydraulic valve **158**.

The fluid pressure in the output line **172** shifts the valve **158** to the flow path **158b**. In this position, the fluid pressure behind the piston **63** is relieved so that the return spring **66** forces the piston toward the proximal end. More specifically, the return spring retracts the inner cannula **17** from the tissue cutting opening

25. The relief of the fluid pressure in line **161** also causes the pressure switch **165** to return to its initial neutral position of flow path **165a**, due to the action of the return spring **166**. In turn, with the flow path **165a**, the pressure input line **168** is no longer connected to the fluid source **152**, so no pressurized fluid is provided to the oscillating hydraulic valve **170**. Since this valve is not spring biased to any particular state, its position does not necessarily change, except under conditions described herein.

Returning to the foot pedal **175** and valve **176, o**nce the foot pedal is released, the biasing spring **177** forces the valve **176** from its flow path **176b** to its normal initial flow path **176a**. In this position the foot pedal input line **179** is no longer connected to the fluid source **152**. When the oscillating valve **170** is at flow path **170a**, the fluid pressure through output line **172** is eliminated. In response to this reduction in fluid pressure, hydraulic valve **158** is shifted to its original flow path **158a** by operation of the return spring **159**. In this position, the cylinder pressure line **161** is again connected to the fluid source **152**, which causes the reciprocating motor **22** to extend the inner cannula **17** to its position blocking the tissue-receiving opening **25**. Thus, in accordance with the present invention, the hydraulic control system **150** starts and finishes the tissue biopsy apparatus **10** with the tissue-receiving opening closed. It is important to have the opening closed once the procedure is complete so that no additional tissue may be trapped

or pinched within the cutting element **11** as the apparatus is removed from the patient.

Thus far the portion of the hydraulic control system **150** that controls the operation of the reciprocating motor **22** has been described. The system **150** also controls the operation of the rotary motor **20**. Again, in the most preferred embodiment, the motor **20** is an air motor. This air motor is controlled by another hydraulic valve **182**. As shown in **FIG. 10**, the initial position of the valve provides a flow path **182a** in which the fluid source **152** is connected to blocked line **183**. However, when the hydraulic valve **182** is pressurized, it moves to flow path **182b** in which the fluid source **152** is connected to the pilot port **140** of the air motor. In this position, pressurized fluid continuously drives the air motor **20**, thereby rotating the inner cannula **17**. It can be noted parathentically that a muffler **M** can be provided on the air motor to reduce noise.

The rotary motor hydraulic valve **182** is controlled by fluid pressure on pressure activation line **180**. This activation line 180 branches from the foot pedal input line **179** and is connected to the foot pedal switch **176**. When the foot pedal **175** is depressed, the switch moves to its flow path **176b**. In this position the pressure activation line **180** is connected to the fluid source **152** so fluid pressure is provided directly to the rotary motor hydraulic valve **182**. As with the other hydraulic valves, the valve **182** includes a

biasing spring **184** that must be overcome by the fluid pressure at the input to the valve.

It should be understood that since the fluid control for the rotary motor **20** is not fed through the oscillating hydraulic valve **170**, the motor operates continuously as long as the foot pedal **175** is depressed. In addition, it should also be apparent that the speed of the rotary motor **20** is not adjustable in the illustrated embodiment. Since the motor **20** is connected directly to the fluid source **152**, which is preferably regulated at a fixed pressure, the air motor actually operates at one speed. On the other hand, as discussed above, the reciprocating motor **22** is supplied through a pressure regulator **154** and a flow control valve **162**. Thus, the speed of reciprocation of the cutting blade **35** is subject to control by the surgeon or medical technician. The reciprocation of the cutting element **11** can be a function of the tissue being sampled, the size of the tissue biopsy sample to be taken, and other factors specific to the particular patient. These same factors generally do not affect the slicing characteristic of the cutting edge **35** achieved by rotating the inner cannula.

The hydraulic control system **150** also regulates the aspiration pressure or vacuum applied through the aspiration conduit, which includes the inner cannula **17**. In the illustrated embodiment, the pressure activation line **180** branches to feed an aspiration valve **185**. The valve is movable from its initial flow path

185a to a second flow path **185b.** In the initial flow path, the fluid source **152** is connected to a blocked line **186**. However, when fluid pressure is applied on line **180**, the valve **185** shifts against the biasing spring **187** to the flow path **185b**. In this path, the venturi element **190** is connected to the fluid source. This venturi element thus generates a vacuum in a vacuum control line **193** and in aspiration line **191**. Again, as with the air motor, the venturi element **190** can include a muffler **M** to reduce noise within the handpiece.

As long as the foot pedal **175** is depressed and the valve **176** is in its flow path **176b**, fluid pressure is continuously applied to the aspiration hydraulic valve **195** and the venturi element **190** generates a continuous vacuum or negative aspiration pressure. As with the operation of the rotary motor, this vacuum is not regulated in the most preferred embodiment. However, the vacuum pressure can be calibrated by a selection of an appropriate venturi component **190**.

When the venturi component **190** is operating, the vacuum drawn on control line **193** operates on vacuum switch **194**. A variable biasing spring **195** initially maintains the vacuum switch **194** at its flow path **194a**. In this flow path, the vacuum input line **196** is not connected to any other line. However, at a predetermined vacuum in control line **193**, the valve moves to flow path **194b**. In this position, the vacuum input line **196** is connected

to pressure line **192**. In the preferred embodiment, the vacuum switch **194** operates in the form of a "go-nogo" switch – in other words, when the aspiration vacuum reaches a predetermined operating threshold, the vacuum switch is activated. When the vacuum switch **184** is initially activated, it remains activated as long as the foot pedal is depressed. Thus vacuum input line **196** is continuously connected to pressure line **192** as long as the foot pedal **175** is depressed.

Looking back to the hydraulic valve **158**, the fluid pressure in line **192**, and ultimately in vacuum input line **196**, is determined by the state of valve **158**. When the valve **158** is in its flow path **158a** in which regulated fluid pressure is provided to the reciprocating motor **22**, the pressure line **192** is dead. However, when the valve **158** moves to flow path **158b**, pressure line **192** is connected to the regulated fluid source. Pressurized fluid then flows from pressure line **192**, through vacuum switch flow path **194b**, through vacuum input line **196** to the left side of oscillating valve **170**, causing the valve to stroke to flow path **170b**. When the oscillating valve **170** is in this flow path, output line **172** is dead, which allows valve **158** to move to its flow path **158a** under the effect of the return spring **159**. In this state, valve **158** allows pressurized fluid to again flow to the reciprocating motor **22** causing it to move through the next cutting stroke.

Thus, when both the valve **158** and the vacuum switch **194** are moved to their alternate states, pressurized fluid passes from line **192**, through vacuum input line **196**, and through an adjustable flow control valve **197** to a second input for the oscillating hydraulic valve **170.** Pressure on the vacuum input line **196** shifts the oscillating valve **170** to its second position for flow path **170b**. In this position, pressurized fluid passing through the foot pedal valve **176** terminates within valve **170**. As a consequence, the pressure in output line **172** drops which allows the hydraulic valve **158** shift back to its original position **158a** under operation of the return spring **159**. In this position, fluid pressure is again supplied to the reciprocating motor **22** to cause the piston **66** to move through its cutting stroke.

It should be appreciated that the oscillating valve **170** is influenced by fluid pressure on lines **168** and **196**, and that these lines will not be fully pressurized at the same time. When the system is initially energized, pressure from source **152** is automatically supplied to reciprocating motor **22** and pressure valve **165**, causing the valve to move to flow path **165b**. In this state, line **168** is pressurized which shifts oscillating valve **170** to the left to state **170a**. The oscillating valve will remain in that state until line **196** is pressurized, regardless of the position of pressure switch **165**. It can also be appreciated that in the preferred embodiment, the fluid pressure on line **196** does not increase to

operating levels until the foot pedal **175** has been depressed and the aspiration circuit has reached its operating vacuum.

In an alternative embodiment, the vacuum switch **194** can be calibrated to sense fine changes in vacuum. In this alternative embodiment, the completion of this return stroke can be determined by the state of the vacuum switch **194**. The vacuum switch **194** can operate as an indicator that a tissue sample has been drawn completely through the aspiration conduit into the collection trap **55**. More specifically, when the vacuum sensed by vacuum switch **194** has one value when the inner cannula is open to atmospheric pressure. This vacuum pressure changes when a tissue sample is drawn into the inner cannula **17**. The vacuum pressure changes again when the tissue is dislodged so that the inner cannula is again open to atmospheric pressure. At this point, the inner cannula **17** is clear and free to resume a cutting stroke to excise another tissue sample. Thus, the vacuum switch **194** can stroke to its flow path **194b** to provide fluid pressure to the left side of the oscillating valve **170**, causing the valve to stroke to flow path **170b**.

It can be appreciated from this detail explanation that the hydraulic control system **150** provides a complete system for continuously reciprocating the axial motor **22**. In addition, the system provides constant continuous pressure to both the rotary motor **20** and the aspiration line **191**, so long as the foot pedal **175**

is depressed. Once the foot pedal is released, fluid pressure in activation line **180** drops which causes the air motor control valve **182** and the aspiration control valve **185** to shift to their original or normal positions in which fluid pressure is terminated to those respective components. However, in the preferred embodiment, pressure is maintained to the reciprocating motor **22** because the motor is fed through valve **158**, which is connected directly to the fluid source **152**.

The hydraulic control system **150** in the illustrated embodiment incorporates five controllable elements. First, the fluid pressure provided to activate the reciprocating motor **22** is controlled through the regulator **154**. In addition, the fluid flow rate to the piston **66** is controlled via the adjustable control valve **162**. The pressure at which the pressure switch **165** is activated is determined by an adjustable return spring **166.** Likewise, the aspiration pressure vacuum at which the vacuum switch **194** is activated is controlled by an adjustable return spring **195**. Finally the adjustable flow control valve **197** controls the fluid flow from the vacuum switch **194** to the oscillating hydraulic valve **170**. Each of these adjustable elements controls the rate and duration of oscillation of the reciprocating motor **22**.

In the preferred embodiment, the pressure switch **165** essentially operates as an "end of stroke" indicators. In other words, when the inner cannula **17** reaches the end of its forward or

cutting stroke, it contacts the cutting board **31**. When it contacts the cutting board, the pressure in the cylinder pressure line **161** changes dramatically. It is this change that causes the pressure switch **165** to change states. This state change causes the oscillating valve **170** to shift valve **158** to terminate fluid pressure to the motor **22**, causing it to stop its cutting stroke and commence its return stroke.

During this return stroke, the excised tissue sample is gradually drawn along the aspiration conduit. Also during the return stroke, fluid pressure bleeds from pressure line **161** and pressure switch **165** and ultimately from line **168** feeding oscillating valve **170**. When this valve strokes, fluid pressure bleeds from valve **158** allowing the valve to return to state **158a** to pressurize the motor **22** for a new cutting stroke. The operation of each of these hydraulic valves introduces an inherent time delay so that by the time the pressure to the reciprocating motor **22** has been restored the aspiration vacuum has pulled the tissue sample through the entire aspiration conduit and into the collection trap **55**.

The use of a hydraulically controlled inner cutting cannula provides significant advantages over prior tissue cutting devices. The use of hydraulics allows most of the operating components to be formed of inexpensive and light-weight non-metallic materials, such as medical-grade plastics. The hydraulic system of the present invention eliminates the need for electrical components,

which means that electrical insulation is unnecessary to protect the patient.

Perhaps most significantly, the hydraulically controlled reciprocation of the inner cutting cannula provides a cleaner and better-controlled cut of biopsy tissue. Since the reciprocating motor **22** is fed from a substantially constant source of pressurized fluid, the pressure behind the motor piston **63** remains substantially constant throughout the cutting stroke. This substantially constant pressure allows the inner cutting cannula to advance through the biopsy tissue at a rate determined by the tissue itself.

In other words, when the cutting edge **35** encounters harder tissue during a cutting stroke, the rate of advancement of the motor piston **63** and therefor the inner cannula **17** decreases proportionately. This feature allows the cutting edge to slice cleanly through the tissue without the risk of simply pushing the tissue. The rotation of the cutting edge can facilitate this slicing action. When the inner cannula encounters less dense tissue, the constant pressure behind the piston **63** allows the cutting edge to advance more quickly through the tissue.

In alternative embodiment, the rotary motor **20** can consist of an electric motor, rather than a pneumatic motor. As depicted in **FIG. 11**, the pressure activation line **180** can be fed to an on-off

pressure switch **198** that is governed by an adjustable bias spring **199**. When the activation line **180** is pressurized the switch **198** establishes a connection between an electric reciprocating motor **20** and a battery pack **200**. Preferably, the battery pack **200** is mounted within the handpiece **12**, but can instead be wired to an external battery contained within the console.

In the preferred embodiment, the tissue biopsy apparatus **10** depicted in **FIG. 1** has an overall length of under sixteen inches (16") and an outer diameter less than one and one quarter inches (1.25"). The outer cannula and therefore the cutting element **11** have a length measured from the handpiece **12** of approximately five inches (5"). The outer cannula preferably has a nominal outer diameter of 0.148" and a nominal inner diameter of 0.136". The inner cannula most preferably has a nominal outer diameter of 0.126" so that it can reciprocate freely within the outer cannula without catching on the tissue cutting opening. The inner cannula has a nominal wall thickness of .010", which yields a nominal inner lumen diameter of about .106."

The length of the tissue-receiving opening determines the length of biopsy sample extracted per each oscillation of the reciprocating motor **22**. In one specific embodiment, the opening has a length of about 0.7", which means that a 0.7" long tissue sample can be extracted with each cutting cycle. In order to accommodate a large number of these biopsy tissue slugs, the

collection trap can have a length of about 2.5" and a diameter of about .05". Of course, the interior volume of the collection trap can vary depending upon the size of each biopsy slug and the amount of material to be collected. In a specific embodiment, the filter disposed within the collection trap **55** manufactured by Performance Systematix, Inc. of Callondoni, MI.

In accordance with a specific embodiment, the cutting stroke for the inner cannula is about 0.905". The return spring **66** within the reciprocating motor **22** is preferably a conical spring to reduce the compressed height of the spring, thereby allow a reduction in the overall length of the hydraulic cylinder **60**. In addition, the return spring **66** can be calibrated so that the return stroke occurs in less than about 0.3 seconds. Preferably, the inwardly beveled surface **36** of cutting edge **35** is oriented at an approximately 30° angle.

The aspiration pressure vacuum is nominally set at 27in.Hg. during the cutting stroke. When the cannula is retracted and the outer lumen **27** is open, the vacuum pressure is reduced to 25in.Hg. This aspiration pressure normally allows aspiration of a tissue sample in less than about 1 second and in most cases in about 0.3 second. In accordance with a most preferred embodiment, the hydraulic control system **150** preferably is calibrated so that the inner cannula dwells at its retracted position for about 0.3 seconds to allow complete aspiration of the tissue

sample. Adjusting the return spring **195** of the vacuum switch **194** can control this dwell rate.

In a preferred embodiment, the inner cannula **17** can advance through the cutting stroke in about two seconds. This stroke speed can be accomplished with a regulated pressure at source **152** of about 20 p.s.i. When the inner cannula reaches the end of its cutting stroke, the pressure can increase at about five p.s.i. per second. Preferably, the return spring **166** of the pressure switch **165** is set so that the end of cutting stroke is sensed within about 0.5 seconds.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character. It should be understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

EXAMPLES

EXAMPLE 1

Eighteen trial biopsies were performed upon patients after obtaining informed consent and preparing the patients according to standard biopsy procedures. In each case, biopsies were performed according to the following procedure. The patient was positioned on her back on the surgical table, and the lesion was

located using ultrasound. A small incision was made in the breast. While viewing the lesion using ultrasound, an early embodiment of the present invention was inserted into the breast with the tissue receiving opening adjacent the lesion. The cutter was engaged to sample and/or remove the lesion. The lesions varied in size from 6 – 22 mm. The surgeon's comments are provided in Table 1.

TABLE 1

Surgeon's Comments Regarding the Use of Early Embodiments of the Present Biopsy Device

Trial Number	Surgeon's Comments
1	Went very well, lesion took approximately 50 seconds to go away
2	Large fatty breast, very difficult to get needle to mass; eventually successfully removed
3	Successfully removed without problems
4	Went very well; lesion gone in 4-5 cores
5	Two lesions attempted (1) lesion easily removed, (2) inner cutter was riding up and catching the opening
6	Only took 4-5 cores to disappear
7	Started getting good cores, then stopped cutting due to secondary electrical break
8	Lesion appeared to be totally gone, cores were up to 25mm in length
9	Only got 4-5 good cores, then stopped cutting due to inner cutter riding up
10	No problems
11	No problems at all
12	Lesion was easily palpable but very mobile which made access difficult. Used tactile sensation to manipulate tumor into aperture which worked very well; very good cores; Took 4.5 minutes but many of the cores were fatty as a lot of the time I was missing the lesion before realizing that palpitation was better
13	Took 3-4 cores then quit cutting, blade was dulled, probably due to deflection of tip downward
14	Went very well, no problems
15	Went well, no problems
16	Went well, no problems
17	Went very well
18	Went very well, the suction tubing collapsed, need stronger tubing;

	filter did fill up requiring stopping to empty, might need larger filter

Table 1 illustrates the success of the present invention in its early stage of development. A majority of the trials, trials 1-6,8,1-12, and 14-18, resulted in a successful removal of the lesion with little to no problems. Lesions were removed quickly and, in some cases, only a few cores were required (see trials 1, 4, and 6). In trial number 8 it was noted that the cores were up to 25mm in length.

In some trials, the surgeon experienced difficulties removing the lesion because the inner cutting blade would ride up and catch on the tissue receiving opening (see trials 5, and 9,). However, this problem has been resolved in the present invention by integrating a crimp in the outer cannula. The crimp forms a dimple that protrudes from the inner surface of the cannula and into the outer lumen. As the inner cannula passes the dimple, the dimple forces the inner cannula away from the tissue-receiving opening and prevents the inner cannula from riding up into the opening. In a further embodiment, the cutting edge of the inner cannula is inwardly beveled. This inwardly beveled surface also helps eliminate risk of catching by guiding the inner cannula back into the hollow outer cannula. In addition, to prevent the deflection of the tip downward, as noted in trial 13, a stiffening element is provided on the outer cannula opposite the tissue-receiving opening.

EXAMPLE 2

Surgeons performing biopsies using the device of this invention and a device having the features of U.S. Patent No. 5,526,822 to Burbank provided feedback as to the efficiency of each device. The surgeons' input was used to calculate the amount of time and the number of strokes necessary to remove a lesion. Table 2 compares the amount of time and the number of strokes necessary to remove comparable lesions using each device.

TABLE 2

Comparison of Removal Times and Number of Strokes of the Present Biopsy Device with the Prior Art Device

		Present Biopsy Device	Prior Art
Removal Times (sec)			
Lesion Diameter	10	80	500
	13	135	845
	16	205	1280
No. of Strokes			
Lesion Diameter	10	16	25
	13	27	42
	16	41	64

This data demonstrates that the present tissue biopsy apparatus consistently removes a lesion with fewer strokes and in less time than the prior cutter. The present tissue biopsy device

performs 80% faster than the prior cutter, which ultimately results in reduced trauma to the tissue.

CONCLUSION

The biopsy devices of this invention reliably, quickly and efficiently sample and remove lesions in tissue.

What is claimed is:

1. A tissue cutting device comprising:

an outer cannula defining a tissue-receiving opening adjacent a distal end thereof;

an inner cannula slidably disposed within said outer cannula and defining a lumen from an open distal end to an open opposite proximal end, said inner cannula defining a cutting edge at said open distal end operable to sever tissue projecting through said tissue-receiving opening;

a first hydraulic rotary motor operably coupled to said inner cannula to rotate said inner cannula within said outer cannula;

a second hydraulic reciprocating motor operably coupled to said inner cannula to translate said inner cannula within said outer cannula while said inner cannula rotates; and

a hydraulic system connecting said first and second hydraulic motors to a source of pressurized fluid.

2. A tissue cutting device comprising:

an outer cannula defining a tissue-receiving opening adjacent a distal end thereof;

an inner cannula slidably disposed within said outer cannula and defining a lumen from an open distal end to an open opposite proximal end, said inner cannula further defining a cutting edge at said open distal end;

a motor assembly operably coupled to said inner cannula for rotationally and reciprocatingly driving said inner cannula within said outer cannula; and

a cutting board disposed at said distal end of said outer cannula, said cutting board formed of a resilient plastic material having a hardness less than a hardness of said inner cannula at said cutting edge but sufficient to substantially prevent permanent deformation of said cutting board under pressure from said cutting edge as said inner cannula rotates and reciprocates against said cutting board.

3. In a cannula sized for insertion in a human body, the cannula having a substantially cylindrical outer wall defining a lumen along a longitudinal axis thereof, in which the lumen is sized to receive a movable cutting member therethrough, the improvement comprising an opening defined through the outer wall communicating with the lumen, said opening having opposite edges extending substantially parallel to the longitudinal axis, each of said edges defining at least one tooth arranged to engage tissue surrounding the cannula when the cannula is inserted into a body.

4. In a cannula sized for insertion in a human body, the cannula having a substantially cylindrical outer wall defining a lumen along a longitudinal axis thereof, in which the lumen is sized to receive a movable cutting member therethrough, the outer wall defining a lateral opening therethrough communicating with the

lumen, the improvement comprising a stiffening member associated with the outer wall adjacent the lateral opening.

5. The improvement in a cannula according to claim 4, wherein said stiffening member includes a longitudinally extending rib defined in the outer wall.

6. The improvement in a cannula according to claim 5, wherein said rib is defined substantially diametrically opposite the lateral opening in the outer wall.

7. In a cannula sized for insertion in a human body, the cannula having a substantially cylindrical outer wall defining a lumen along a longitudinal axis thereof, in which the lumen is sized to receive a movable cutting member therethrough, the outer wall defining a lateral opening therethrough communicating with the lumen, the improvement comprising a dimple associated with the outer wall and projecting into the lumen adjacent the lateral opening, said dimple sized to fit between the cutting member and the outer wall when the cutting member is within the lumen.

8. The improvement in a cannula according to claim 7, wherein said dimple is formed by a crimp in the outer wall of the cannula.

9. A tissue cutting device comprising:

an outer cannula defining an outer lumen and a tissue-receiving opening adjacent a distal end of said outer cannula communicating with said outer lumen;

an inner cannula slidably disposed within said outer lumen and defining an inner lumen from an open distal end to an open opposite proximal end, said inner cannula defining a cutting edge at said open distal end operable to sever tissue projecting through said tissue-receiving opening;

a first motor operably coupled to said inner cannula to move said inner cannula in a first direction within said outer lumen;

means for supporting said first motor for movement with said inner cannula in a second direction different from said first direction; and

a second motor operably coupled to said means for supporting to move said first motor, and thereby said inner cannula, in said second direction while said first motor moves said inner cannula in said first direction.

10. A tissue cutting device comprising:

an outer cannula defining an outer lumen between a distal end and an opposite proximal end, and further defining a tissue-receiving opening adjacent said distal end communicating with said lumen;

a cutting member slidably disposed within said outer lumen, said cutting member defining an inner lumen therethrough

between a distal end and an opposite proximal end, and further defining a cutting edge at said distal end of said cutting member;

a handpiece supporting a drive mechanism operably coupled to said cutting member to move said cutting edge across said tissue-receiving opening to sever tissue projecting therethrough;

a vacuum source in fluid communication with said proximal end of said cutting member; and

a hub having a distal end attached to said proximal end of said outer cannula, and a proximal end detachably mounted to said handpiece to permit separation of said outer cannula from said handpiece and said cutting member.

11. A tissue cutting device comprising:

an outer cannula defining an outer lumen between a distal end and an opposite proximal end, and further defining a tissue-receiving opening adjacent said distal end communicating with said lumen;

a cutting member slidably disposed within said outer lumen, said cutting member defining an inner lumen therethrough between a distal end and an opposite proximal end, and further defining a cutting edge at said distal end of said cutting member;

a handpiece supporting a drive mechanism operably coupled to said cutting member to move said cutting edge past said tissue-receiving opening to sever tissue projecting therethrough;

a vacuum source in fluid communication with said inner lumen at said proximal end of said cutting member; and

a hub having a distal end attached to said proximal end of said outer cannula, and a proximal end mounted to said handpiece, said hub defining a leak path between said outer lumen of said outer cannula and atmospheric air when said distal end of said outer cannula is disposed within a body and said hub is disposed outside the body.

12. A tissue cutting system comprising:

an outer cannula defining a tissue-receiving opening adjacent a distal end thereof;

an inner cannula slidably disposed within said outer cannula and defining a lumen from an open distal end to an open opposite proximal end, said inner cannula defining a cutting edge at said open distal end operable to sever tissue projecting through said tissue-receiving opening;

a cutting board disposed at said distal end of said outer cannula distal from said tissue-receiving opening, said cutting board configured to conform to said cutting edge for impact cutting of tissue between said cutting edge and said cutting board;

a piston disposed within a hydraulic cylinder and operably coupled to said inner cannula to move said inner cannula within said outer cannula toward said cutting board;

a return spring disposed within said cylinder and operable against said piston to move said piston in a direction away from said cutting board;

a source of pressurized fluid connected to said hydraulic cylinder having a first state providing pressurized fluid to said cylinder and a second state permitting fluid to bleed from said cylinder; and

a pressure switch coupled to said source of pressurized fluid to switch said source between said first state and said second state as a function of the magnitude of the fluid pressure within said cylinder.

13. A tissue cutting device comprising:

an outer cannula defining a tissue-receiving opening adjacent a distal end thereof;

an inner cannula slidably disposed within said outer cannula and defining a lumen from an open distal end to an open opposite proximal end, said inner cannula defining a cutting edge at said open distal end operable to sever tissue projecting through said tissue-receiving opening;

a cutting board disposed at said distal end of said outer cannula and cooperating with said cutting edge of said inner cannula to sever tissue under pressure from said cutting edge against said cutting board;

a hydraulic reciprocating motor operably coupled to said inner cannula to advance said inner cannula within said outer cannula against said cutting board; and

a hydraulic system connecting said hydraulic motor to a source of pressurized fluid to provide a substantially constant fluid pressure to said motor as said motor advances said inner cannula.

ABSTRACT OF THE DISCLOSURE

A disposable tissue removal device comprising a cutting element mounted to a handpiece. The cutting element includes an outer cannula defining a tissue-receiving opening and an inner cannula concentrically disposed within the outer cannula. The outer cannula has a trocar tip at its distal end and a cutting board snugly disposed within the outer cannula. The inner cannula defines an inner lumen that extends the length of the inner cannula and terminates in an inwardly beveled, razor-sharp cutting edge. The inner cannula is driven by both a rotary motor and a reciprocating motor. At the end of its stroke, the inner cannula makes contact with the cutting board to completely sever the tissue. An aspiration vacuum is applied to the inner lumen to aspirate excised tissue through the inner cannula and into a collection trap that is removably mounted to the handpiece. The rotary and reciprocating motors are hydraulically powered through a hydraulic circuit. The hydraulic circuit includes a foot pedal that initiates aspiration vacuum, rotary motion and reciprocation of the inner cannula. The hydraulic circuit is configured so that the inner cannula closes the tissue-receiving opening before the foot pedal is depressed and automatically after the foot pedal is released.

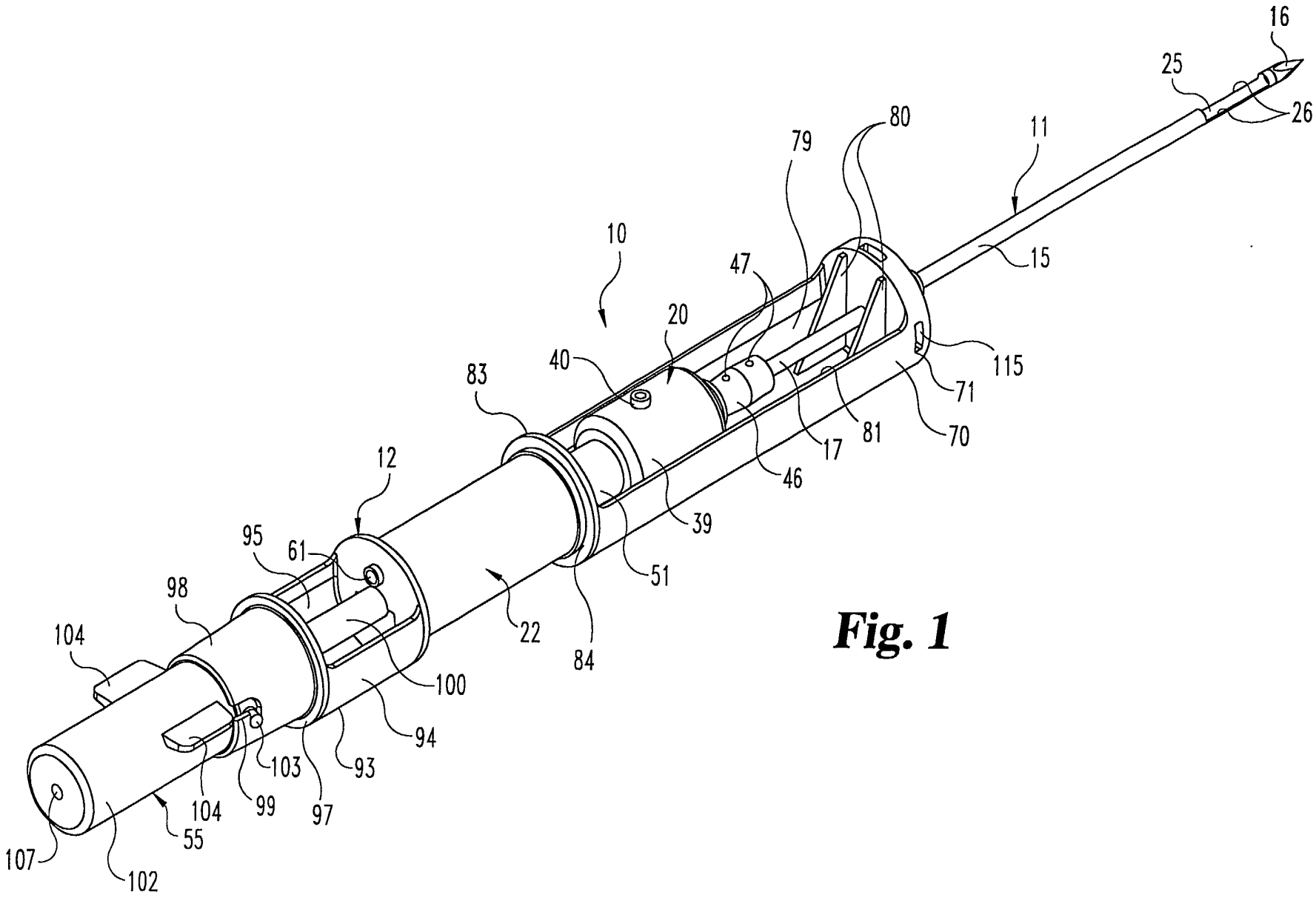

Fig. 1

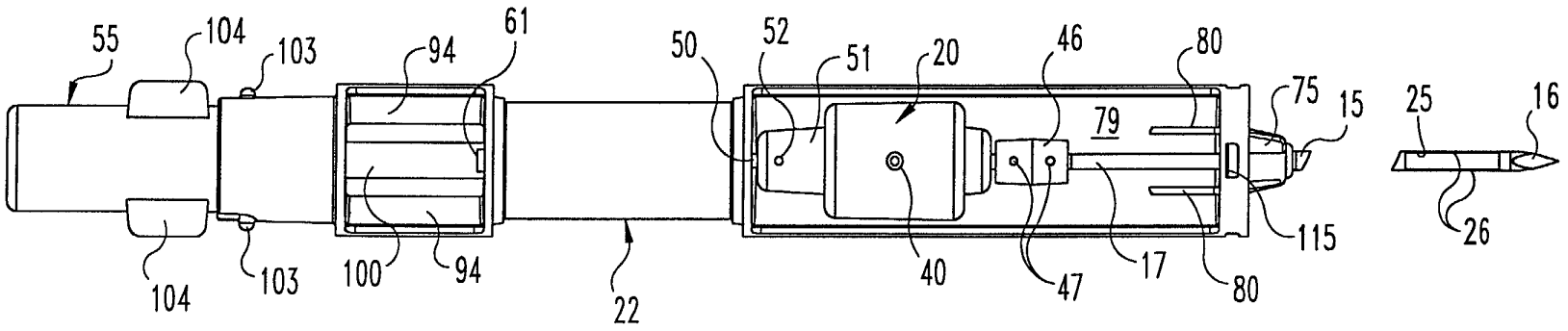
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Fig. 2

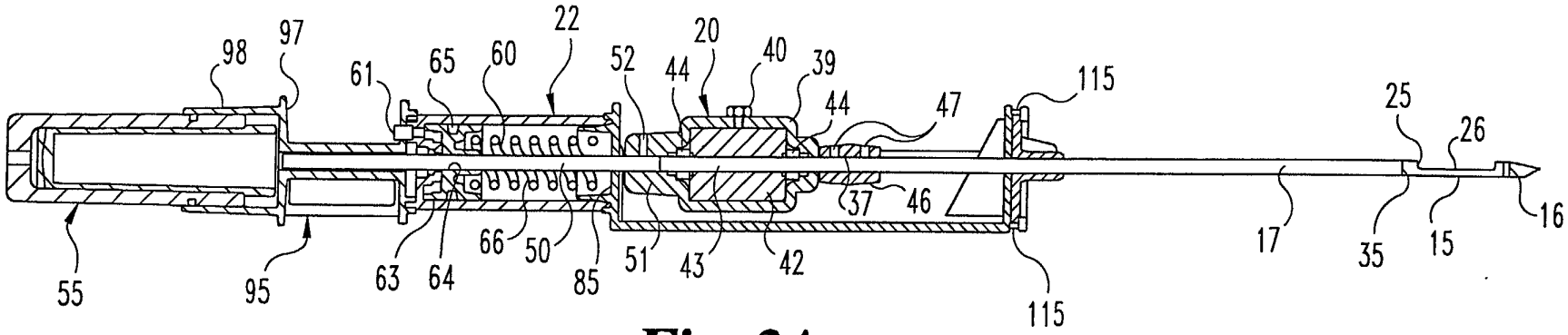

Fig. 3A

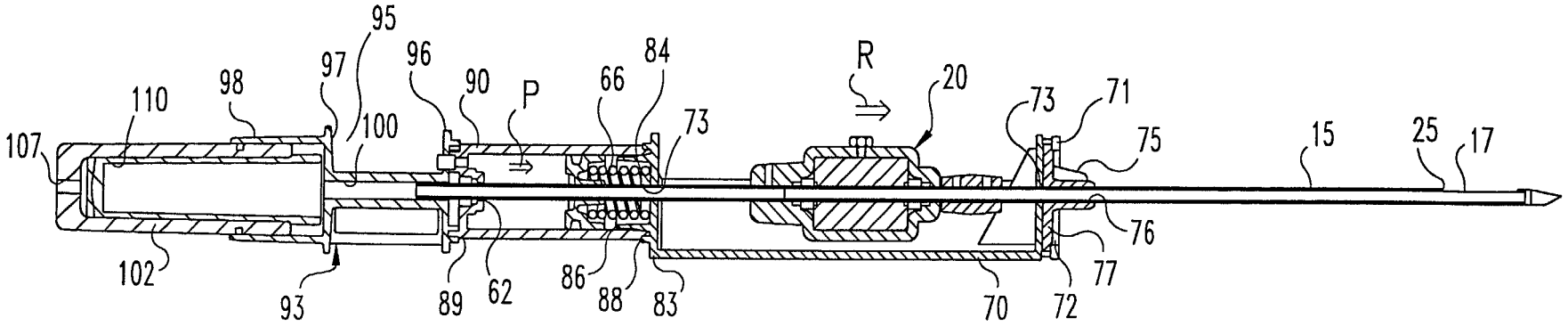

Fig. 3B

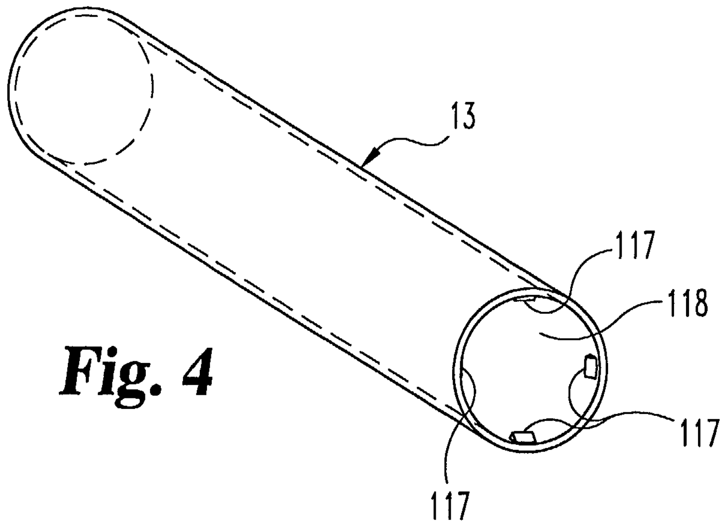

Fig. 4

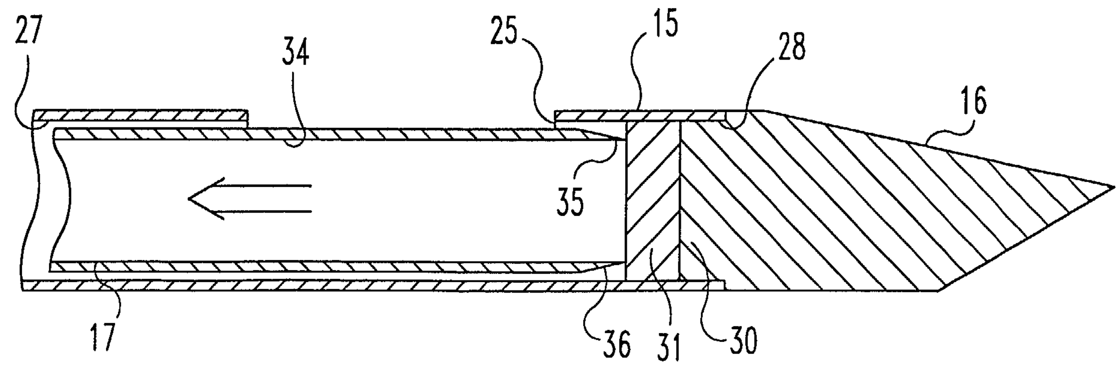

Fig. 5

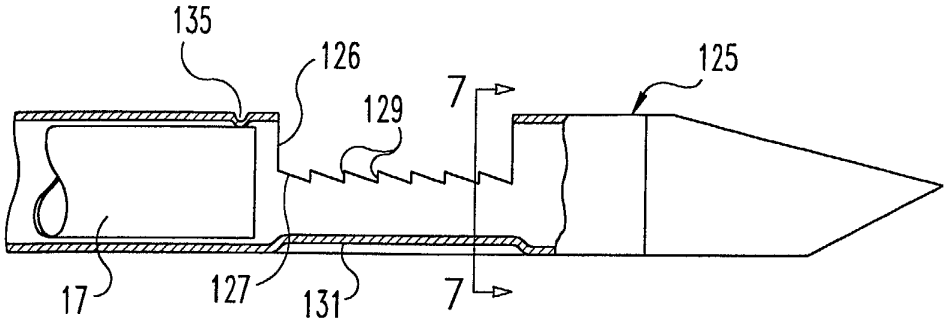

Fig. 6

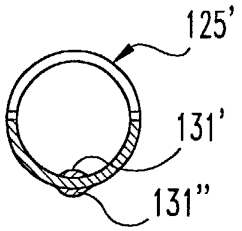

Fig. 8

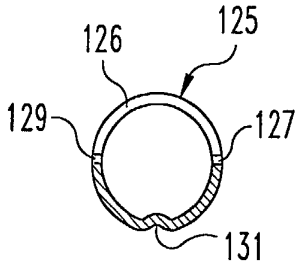

Fig. 7

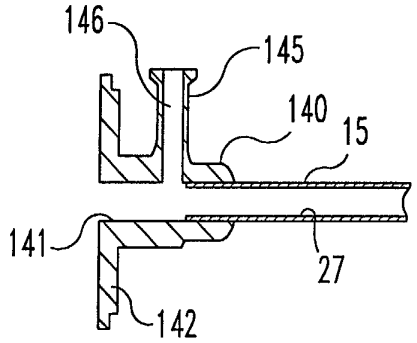

Fig. 9

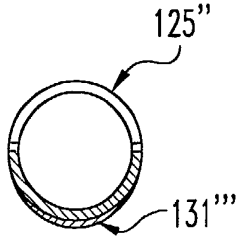

Fig. 8(a)

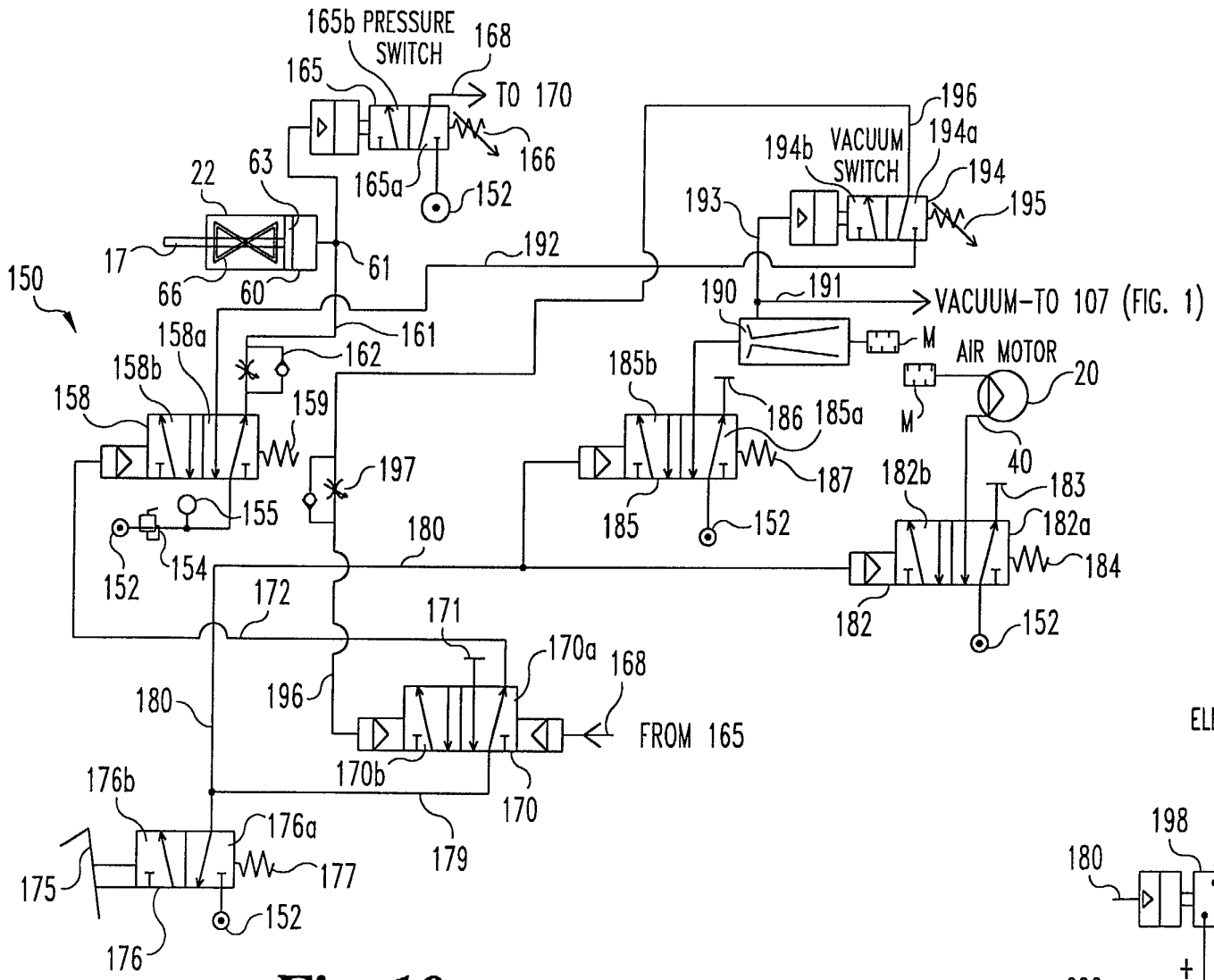

Fig. 10

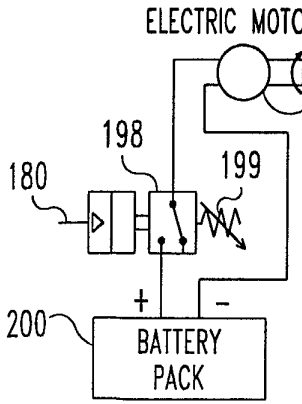

Fig. 11

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

[X] Declaration Submitted with Initial Filing OR [ ] Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	SUROS-3
First Named Inventor	Michael E. Miller, et al.
COMPLETE IF KNOWN	
Application Number	
Filing Date	November 6, 2000
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

BIOPSY APPARATUS

(Title of the Invention)

the specification of which
[X] is attached hereto
OR
[ ] was filed on (MM/DD/YYYY) [ ] as United States Application Number or PCT International Application Number [ ] and was amended on (MM/DD/YYYY) [ ] (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S C. 119(a)-(d) or 356(b) of any foreign application(s) for patent or inventor's certificate, or 356(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]

[ ] Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)

[ ] Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02C attached hereto.

As a named inventor, I hereby appoint the following registered practioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☐ Customer Number [ ] → Place Customer Number Bar Code Label here
OR
[X] Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
Deborah R. Beck	37,370	Michael D. Smith	40,181
Michael D. Beck	32,722	Michael D. Schwartz	44,326
Jeffrey A. Michael	37,394	Robert C. Hyta	46,791

[X] Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Michael E.	Miller

Inventor's Signature						Date	
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☒ Additional inventors are being named on the ___ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto

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REGISTERED PRACTITIONER INFORMATION (Supplemental Sheet)

Name	Registration Number	Name	Registration Number
Rozell Williams	44,403		
Arthur R. Whale	18,778		
Kevin R. Erdman	33,687		

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DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 1 of 1

Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

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Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

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Inventor's Signature						Date	
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Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname

Inventor's Signature						Date	
Residence: City		State		Country		Citizenship	
Post Office Address							
Post Office Address							
City		State		ZIP		Country	

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